

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Solomon S. Steiner, Rodney J. Woods, and Joseph W. Sulner

Serial No.: Continuation of 10/224,761 Art Unit: Not Yet Assigned

Filed: November 21, 2003 Examiner: Not Yet Assigned

For: *PURIFICATION AND STABILIZATION OF PEPTIDE AND PROTEIN
PHARMACEUTICAL AGENTS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including two (2) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/224,761, filed August 20, 2002, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however. Copies of the newly cited documents, which are identified with an asterisk (*), are enclosed.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,352,461	10-04-1994	Feldstein et al.	424/493
5,503,852	04-02-1996	Steiner et al.	424/493
5,547,929	08-20-1996	Anderson Jr. et al.	514/3
5,888,477	03-30-1999	Gonda et al.	424/45
5,976,569	11-02-1999	Milstein	424/451
6,071,497	06-06-2000	Steiner et al.	424/45
*6,331,318	12-18-2001	Milstein	424/490
*6,395,774	05-28-2002	Milstein	514/490
6,428,771	08-06-2002	Steiner, et al.	424/45

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 96/36314 A2	11-21-1996	Pharmaceutical Discovery Corporation	PCT
WO 99/52506 A1	10-21-1999	Aventis Research & Technologies	PCT
0 220 958 A2	05-06-1987	Eli Lilly and Company	EP

Publications

CERASI, et al., "Decreased sensitivity of the pancreatic beta cells to glucose in prediabetic and diabetic subjects. A glucose dose-response study," *Diabetes* 21(4): 224-34 (1972).

GUPTA, et al., "Contemporary approaches in aerosolized drug delivery to the lung," *Journal of Controlled Release* 17:129-148 (1991).

KATCHALSKI, et al., "Synthesis of lysine anhydride," *J. Amer. Chem. Soc.* 68: 879-80 (1946).

KOPPLE, et al., "A convenient synthesis of 2,5-piperazinediones," *J. Org. Chem.* 33(2): 862-64 (1968).

LEAHY, "Beta-cell dysfunction in type II diabetes mellitus," *Curr. Opin. Endocrinol. Diabetes* 2(4): 300-306 (1995).

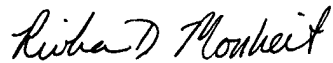
PFEIFFER, "Insulin secretion in diabetes mellitus," *Am. J. Med.* 70(3): 579-88 (1981).

POLONSKY, et al., "Abnormal patterns of insulin secretion in non-insulin-dependent diabetes mellitus," *N. England J. Med.* 318(19): 1231-39 (1988).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Rivka D. Monheit
Reg. No. 48,731

Dated: November 21, 2003

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known			
				Application Number		Continuation of 10/224,761	
				Filing Date		November 21, 2003	
				First Named Inventor		Solomon S. Steiner	
				Group Art Unit			
				Examiner Name			
Sheet	1	of	2	Attorney Docket Number	PDT 120/121 DIV CON		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,352,461		Feldstein et al.	10-04-1994	
		5,503,852		Steiner et al.	04-02-1996	
		5,547,929		Anderson Jr. et al.	08-20-1996	
		5,888,477		Gonda et al.	03-30-1999	
		5,976,569		Milstein	11-02-1999	
		6,071,497		Steiner et al.	06-06-2000	
		6,331,318		Milstein	12-18-2001	
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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 96/36314		Pharmaceutical Discovery Corporation	11-21-1996		
		PCT	WO 99/52506		Aventis Research & Technologies	10-21-1999		
		EP	0 220 958		Eli Lilly and Company	05-06-1987		

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¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

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Sheet	2	of	2	Attorney Docket Number	PDT 120/121 DIV CON

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		CERASI, et al., "Decreased sensitivity of the pancreatic beta cells to glucose in prediabetic and diabetic subjects. A glucose dose-response study," <i>Diabetes</i> 21(4): 224-34 (1972).	
		GUPTA, et al., "Contemporary approaches in aerosolized drug delivery to the lung," <i>Journal of Controlled Release</i> 17:129-148 (1991).	
		KATCHALSKI, et al., "Synthesis of lysine anhydride," <i>J. Amer. Chem. Soc.</i> 68: 879-80 (1946).	
		KOPPLE, et al., "A convenient synthesis of 2,5-piperazinediones," <i>J. Org. Chem.</i> 33(2): 862-64 (1968).	
		LEAHY, "Beta-cell dysfunction in type II diabetes mellitus," <i>Curr. Opin. Endocrinol. Diabetes</i> 2(4): 300-306 (1995).	
		LIAN, et al., "A self-complementary, self-assembling microsphere system: application for intravenous delivery of the antiepileptic and neuroprotectant compound felbamate," <i>J Pharm Sci</i> 89:867-875 (2000).	
		PFEIFFER, "Insulin secretion in diabetes mellitus," <i>Am. J. Med.</i> 70(3): 579-88 (1981).	
		POLONSKY, et al., "Abnormal patterns of insulin secretion in non-insulin-dependent diabetes mellitus," <i>N. England J. Med.</i> 318(19): 1231-39 (1988).	

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